

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TAKEDA PHARMACEUTICAL
COMPANY LIMITED, and TAKEDA
PHARMACEUTICALS U.S.A., INC.

Plaintiffs,

C.A. No. 20-cv-8966-SRC-CLW

V.

NORWICH PHARMACEUTICALS, INC.,
ALVOGEN PB RESEARCH AND
DEVELOPMENT LLC, ALVOGEN
PHARMA US, INC., and ALVOGEN
GROUP, INC.

Defendants.

**DECLARATION IN SUPPORT OF DEFENDANTS' MOTION TO
DISMISS FOR IMPROPER VENUE AND FAILURE TO STATE A CLAIM**

I, Paul H. Fackler, Ph.D., declare as follows:

1. I submit this declaration in support of Norwich Pharmaceuticals, Inc. (“Norwich”), Alvogen PB Research and Development LLC (“Alvogen PB”), Alvogen Pharma US, Inc. (“Alvogen US”), and Alvogen Group, Inc.’s (“Alvogen Group”) Motion to Dismiss for Improper Venue and Failure to State a Claim.

2. I have been employed by Alvogen, Inc. since October 30, 2018. Alvogen, Inc. personnel support the research and development services that Alvogen PB provides to various entities, including Norwich. To date, Alvogen PB has developed two filed ANDA products for Norwich.

3. My current job title is Vice President of Clinical R&D. My prior job title was Vice President of Clinical Pharmacology and Development. In that position and in my current position, I have had a leading role in the clinical testing services that Alvogen PB provides.

4. The information in this declaration is based on my personal knowledge and information made available to me while performing my work for Alvogen PB. If called as a witness, I could testify competently to the matters discussed below.

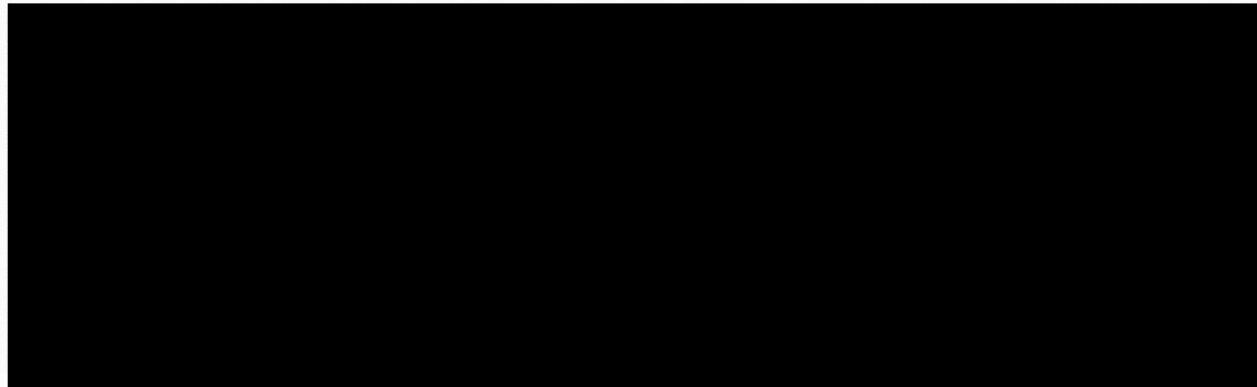
5. I currently lead the Clinical R&D group [REDACTED]
[REDACTED] Norwich's ANDA No. 214547 ("the Norwich ANDA"), which seeks approval from the Food and Drug Administration ("FDA") for Lisdexamfetamine Dimesylate Capsules, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg ("the Norwich Proposed Product").

6. Other members of what is now the Clinical R&D group [REDACTED]
[REDACTED] Norwich Proposed Product included Meena Venugopal, Nimesh Patel, Bhavesha Patel, and Komal Mulchandani.¹

7. I have reviewed the Study Protocols and Clinical Study Reports that I understand have been submitted to the Court as Exhibits 15-19 of Plaintiffs' Opposition to Defendants' Motion to Dismiss. The Clinical R&D group that I lead [REDACTED]
[REDACTED]

8. The Studies and Protocols may erroneously suggest that I and other members of the biopharmaceutics group work for Norwich. For example, Exhibit 19 contains the following excerpt:

¹ Meena Venugopal, Bhavesha Patel, and Komal Mulchandani have since left Alvogen, Inc. and are no longer employed by any Alvogen entity.



9. Although my name, job title², and contact information are correct, the Clinical Study Report that is Exhibit 19 should have specified that [REDACTED]

[REDACTED] As the Norwich ANDA indicates, the Norwich Proposed Product was

[REDACTED] and both [REDACTED]

[REDACTED]

[REDACTED] (Pls.' Ex. 9, NPILDX_00002274 at -2277.)

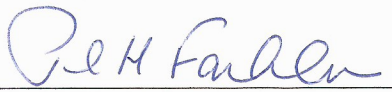
10. The same is true for Meena Venugopal, Nimesh Patel, Bavesha Patel, Komal Mulchandani, and all other members of what is now the [REDACTED] Clinical R&D group. The Study Protocols and Clinical Study Reports should not have indicated that they held their respective job titles at Norwich.

11. Similarly, [REDACTED]
[REDACTED] should have included Norwich's correct address in New York, as reflected on pages of Plaintiffs' Ex. 9 (NPILDX_00002274-2277), or indicated that the 10B Bloomfield Avenue address in Pine Brook was for Alvogen PB, and not Norwich.

12. I have never been employed by Norwich.

² At the time, my title was VP Clinical Pharmacology and Development. As I stated earlier, my current title is VP Clinical R&D.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on this 26th day of October, 2020.



Paul H. Fackler, Ph.D.